



This document is scheduled to be published in the Federal Register on 10/30/2013 and available online at <http://federalregister.gov/a/2013-25711>, and on [FDsys.gov](http://FDsys.gov)

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-13GX]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Assessment of a Comprehensive Human Immunodeficiency Virus (HIV) Clinic-Based Intervention to Promote Patients' Health and Reduce Transmission Risk - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This research is funded by the CDC and the National Institute of Mental Health (NIMH). The purpose of the project is to implement and

evaluate an HIV clinic-based intervention, the goals of which are to increase the percentage of patients who have an undetectable viral load, who are adherent to antiretroviral therapy (ART), who attend clinic regularly for primary care, and practice safer sexual behaviors. Realizing these goals will promote HIV patients' health and reduce risk of transmitting HIV to others. These are objectives of the National HIV/AIDS Strategy and goals of the strategic plan of the Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention.

The project will be conducted at six university-affiliated HIV clinics in the United States: (1) Baylor College of Medicine, Houston, (2) Boston Medical Center, (3) University of Alabama, Birmingham, (4) University of California at San Diego, (5) University of Miami Medical School, and (6) University of Washington in the state of Washington. This proposed data collection will occur over 3 years.

The intervention that is part of this project focuses primarily on HIV patients who have a detectable viral load, i.e., their viral load is not as low as it can be and is not fully controlled. The intervention components include: (1) brief counseling from medical providers during primary care visits informed by a behavioral screener completed by patients; (2) a computer-based intervention (CBI) in which patients see short videos of HIV medical providers (not their own providers) talking about the importance of regular

clinic attendance, adherence to ART, and safer sex; and (3) one-on-one counseling from a prevention specialist if needed.

The following data will be collected in this project:

- A data manager at each clinic will electronically transmit patient clinical data to CDC using a unique study identification code as the only means of identifying a patient's data. The data files sent to CDC will not contain any medical record numbers, names, or social security numbers. The information will be encrypted and stored in a secure CDC server. The data collected from patients include (1) a behavioral screener self-administered by patients each time they have a primary care visit. Patients complete the screener in the waiting room before seeing their primary care provider. (2) CBI assessment items on demographic factors, clinic attendance, ART status, ART adherence, and sexual risk behavior that are completed before patients see the CBI videos. Patients with detectable viral loads will be asked to do the CBI three times, spaced approximately three months apart. Patients' CBI responses are not shared with their clinic providers. (3) On a quarterly basis, 50 patients at each clinic will be asked to complete a brief exit survey after their medical exam, asking about topics that the provider may have discussed with them at their medical visit (e.g., adherence, clinic attendance).

- Data collected from primary care medical providers includes a quarterly survey asking them to indicate the types of topics/issues they discussed with their HIV patients.

There are no costs to respondents other than their time. The total annualized burden hours are 3,378.

**Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)
Data manager at clinic	Electronic transmittal of clinical variables archived in clinic databases (no form)	6	4	24
Patient	Behavioral screener (patients with detectable or undetectable VL; paper form)	6,315	4	5/60
Patient	CBI assessment items for patients with detectable VL (electronic form)	2,069	3	5/60
Patient	Patient exit survey (electronic form)	1,200	1	5/60
Primary care provider	Provider survey (electronic form)	120	4	10/60

---

LeRoy Richardson  
Chief, Information Collection Review Office

Office of Scientific Integrity  
Office of the Associate Director for Science  
Office of the Director  
Centers for Disease Control and Prevention

[FR Doc. 2013-25711 Filed 10/29/2013 at 8:45 am;  
Publication Date: 10/30/2013]